

REMARKS/ARGUMENTS

Claims 3 and 13-18 are pending in the application and stand rejected. The applicants have amended claims 3, 13, 15-16 and 18 as shown above. No new matter is added by the amendments. In view of the foregoing amendments and following discussion, the applicants submit that all pending claims are in condition for allowance.

On page 3 the Examiner rejected claim 18 under 35 U.S.C. § 112, second paragraph, as being indefinite. The applicants have overcome this rejection by the foregoing amendment to claim 18. Accordingly the applicants respectfully request the Examiner withdraw the rejection.

On page 4 the Examiner rejected claims 3 and 13-17 under 35 U.S.C. § 103(a) as being unpatentable over Anderskewitz et al. (U.S. Patent No. 5,731,332) in view of Gregory et al. (U.S. Patent No. 6,172,096). The applicants have amended claims 3, 13 and 15-16. The combination of Anderskewitz et al. and Gregory et al. does not result in the claimed invention. Amended claim 3 recites, in part, a pharmaceutical composition for the treatment of inflammation consisting essentially of the compound of formula (IA) and meloxicam of formula or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier or excipient, wherein the composition has a weight ratio of formula (IA) to meloxicam of 1:20.

Amended claim 13 recites, in part, a pharmaceutical kit for the treatment of inflammation consisting essentially of two separate unit dosage forms (A) and (B): (A) comprises a composition containing a LTB₄ antagonist, of formula (IA) or a tautomer, a pharmaceutically acceptable salt or solvate thereof; and (B) comprises meloxicam, and optionally a pharmaceutically acceptable carrier or excipient, wherein the composition has a weight ratio of formula (IA) to meloxicam of 1:20.

By the foregoing amendments to claims 3 and 13 the applicants submit the claims are commensurate in scope with the super-additive results disclosed on lines 20-25 of page 16 of the specification. Specifically, amended claims 3 and 13 recite the weight ratio of formula (IA):meloxicam at which a synergistic effect was observed.

Regarding the rejection of the dosage amount / ratios the applicants have amended claims 15 and 16. Amended claim 15 recites a pharmaceutical formulation according to claim 3 wherein a single application dose contains 1-250 mg of formula (IA) and 20-5000 mg of meloxicam.

Amended claim 16 recites a pharmaceutical formulation according to claim 3 wherein a single application dose contains 1-200 mg of formula (IA) and 20-4000 mg of meloxicam.

By the foregoing amendments to claims 15 and 16 the applicants submit the claims are commensurate in scope with the super-additive results disclosed on lines 20-25 of page 16 of the specification. Specifically, amended claims 15 and 16 recite single application doses with a weight ratio of formula (IA):meloxicam (i.e., 1:20) at which a synergistic effect was observed.

On page 5 the Examiner alleges the unexpected results relating to the treatment of inflammation demonstrated in the present specification are only realized when one practices a method of treating inflammation which includes a step of administering the active agents to a host and that because the present claims are not limited by an intended use or function or a step of administration the present claims are not commensurate in scope with such results. A showing of “unexpected results”, i.e., “to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected” rebuts a prima facie case of obviousness. *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). The applicants submit the claimed composition (i.e., formula (IA) and meloxicam) would not be obvious to a skilled artisan because the prior art does not direct a skilled artisan to the composition at the claimed weight ratio (i.e., a ratio of formula (IA):meloxicam of 1:20) which creates the unexpected result.

As discussed in the previous Response to the Office Action filed September 17, 2007, neither Anderskewitz et al. nor Gregory et al. teaches a LTB₄ antagonist with a COX-2 inhibitor with any synergistic effect of such a combination therapy. It would not have been obvious for one of ordinary skill in the art to combine the LTB₄ antagonist of formula (IA) and the COX-2 inhibitor meloxicam at the specific weight ratio in amended claims 3 and 13 resulting in a synergistic effect. In light of the above amendments and discussion claims 3 and 13 are not obvious over Anderskewitz et al. in view of Gregory et al. and are therefore allowable. Claims 14-18 which depend from claim 3 and recite further limitations are also not obvious and are thus allowable. Accordingly the applicants respectfully request the Examiner withdraw the rejection.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. The fees for an RCE and a two (2) month extension of time are

included herewith. In the event that there are any fees dues and owing in connection with this matter, please charge the same to our Deposit Account No. 11-0223.

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Respectfully submitted,

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